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European multicentre randomised controlled clinical trial: Heavy Silicone Oil (HSO) versus standard silicone oil as long term vitreous tamponade

Submission date
20/12/2005

Registration date
20/12/2005

Last Edited
14/07/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OZR-2004-06; NTR185

Study information

Scientific Title

Acronym
HSO-Study

Study objectives
Efficacies of heavy silicone oil and of standard silicone oil, as long-term vitreous tamponade in patients with complex ablatio retinae, are equivalent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee before participants were recruited

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Retinal detachment, proliferative vitreoretinopathy

Interventions
Randomised to:
1. Heavy silicone oil, or
2. Standard silicone oil
As long-term vitreous tamponade.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Heavy silicone oil, standard silicone oil

Primary outcome measure
Complete retinal reattachment and Early Treatment Diabetic Retinopathy Study (ETDRS) vision after 12 months.

Secondary outcome measures
Number of resurgeries within 12 months

Overall study start date
01/05/2005

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Ablatio retinae with proliferative vitreoretinopathy (PVR)
2. Giant tear below 10 - 12 hours

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
1. Defects above 10 - 12 hours
2. Proliferative diabetic retinopathy
3. Trauma
4. Uveitis
5. Glaucoma
6. Monoculus

Date of first enrolment
01/05/2005

Date of final enrolment

01/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Oogziekenhuis Rotterdam
Rotterdam
Netherlands
3011 BH

Sponsor information

Organisation
Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02hjc7j46

Funder(s)

Funder type
Research organisation

Funder Name
Foundation of Scientific Research at the Eye Hospital (Stichting Wetenschappelijk Onderzoek het Oogziekenhuis) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration